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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,311	07/19/2001	Heiner Max	Beiersdorf 733-KGB	9953

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,311	MAX ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24,25,27-29 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24,25,27-29 and 31-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on August 19, 2004 wherein claims 24, 27-29 and 31-38 have been amended since claim 1 has been amended. Claims 1-23, 26, and 30 have been cancelled previously.

Currently, claims 24-25, 27-29 and 31-38 are pending in this application.

Claims 24-25, 27-29 and 31-38 are examined on the merits herein.

Applicant's amendment filed August 19, 2004 with respect to the rejection of claims 24, 27-29 and 31-38 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitations, i.e., " long chain fatty acid monoglycerides and diglycerides that are **partially neutralized** with citric acid, C12-C15-alkyl benzoate, and unbranched C5-C24 fatty acids or the corresponding alcohols " in claim 24 of record stated in the Office Action dated May 19, 2004 have been fully considered and found persuasive to remove the rejection since the indefinite recitations have been removed from the claims. Therefore, the said rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-25, 27-29 and 31-38 as amended now are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, essentially for reasons of record stated in the Office Action dated May 19, 2004.

Applicant's amendment submitted August 19, 2004 with respect to amended claims 24-25, 27-29 and 31-38 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "one oil phase selected from the group consisting of long chain fatty acid monoglycerides and diglycerides that are partially neutralized with citric acid, C12-C15-alkyl benzoate, and unbranched C5-C24 fatty acids or the corresponding alcohols... ratio ...in the range between about 0.01 to 10" (emphases added). The original specification merely discloses that for example, "oils, such as triglycerides of capric or caprylic acid, but preferably castor oil" and "The oil phase is particularly preferably chosen from the group consisting of 2-ethylhexyl isostearate, octyldodecanol, isotridecyl isononanoate, isoeicosane, 2-ethylhexyl cocoate, C12-15-alkyl benzoate, caprylic/capric triglyceride, dicaprylyl ether" and "Particularly advantageous mixtures are those of C12-15-alkyl benzoate and 2-ethylhexyl isostearate, those of C12-15-alkyl benzoate and isotridecyl isononanoate, and those of C12-15-alkyl benzoate, 2-ethylhexyl isostearate and isotridecyl isononanoate" (see for example page 13-14 of the specification). Nowhere can the recitation "long chain fatty acid **monoglycerides** and **diglycerides** or **diglycerides** that are partially neutralized with citric acid, C12-C15-alkyl benzoate, and unbranched C5-C24 fatty acids" be found in the specification. One of skill in the art

would recognize that monoglycerides and diglycerides or long chain fatty acid monoglycerides and diglycerides are separate and different compounds from triglycerides of capric or caprylic acid.

Moreover, the specific **range** of ratio, 0.01 to 10, is not seen to be taught in the specification as originally filed.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Response to Argument

Applicant's arguments filed August 19, 2004 with respect to this rejection made under U.S.C. 112, first paragraph, as containing new matter of record in the previous Office Action have been fully considered but are not deemed persuasive as further discussed below.

Applicant asserts that monoglycerides and diglycerides, or long chain fatty acid monoglycerides and diglycerides, and the specific **range** of ratio, 0.01 to 10, are inherent function, theory, or advantage. Contrary to Applicant's assertion, one of skill in the art would recognize that monoglycerides and diglycerides or long chain fatty acid monoglycerides and diglycerides are separate and distinct compounds from triglycerides of capric or caprylic acid. Moreover, the specification as originally filed fails to disclose any the specific **range** of ratio, 0.01 to 10. More importantly, these new limitations are not deemed to be inherent function, theory, or advantage.

For the above stated reasons, said claims are properly rejected made under 35 U.S.C. 112, first paragraph, for inserting new matter into the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for same reasons of record stated in the Office Action dated May 19, 2004.

The recitation " long chain fatty acid monoglycerides and diglycerides that are **partially neutralized** with citric acid, C12-C15-alkyl benzoate, and unbranched C5-C24 fatty acids or the corresponding alcohols " in claim 25 renders these claims indefinite, since one of ordinary skill in the art, e.g., a chemist, would not understand how this neutralization would take place and what would be products from this neutralization. Thus, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to what would be encompassed thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-25, 27-29 and 31-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference by Sanchez et al. (5,296,472) in view of Lucas et al. (5,928,631) for same reasons of record stated in the Office Action dated May 19, 2004.

Sanchez et al. discloses methods for delipidation of skin and/or hair or for controlling the excessive buildup of sebum on mammalian skin or hair comprising topically applying to skin and/or hair an effective amount of a composition comprising a cyclodextrin component having one or more cyclodextrin. See abstract, col.1 lines 14-17 and 31-33, col.3 lines 13-14 and 61-65, and col.8-9 Example 3-5, in particular. Sanchez et al. also discloses that the effective amounts of cyclodextrin component broadly including α-, β-, γ-cyclodextrins in the topical composition therein are about 1-30% by weight and most prefereably 10% by weight. See col.2 lines 57-63 in particular. Sanchez et al. further discloses that the cyclodextrin compositions therein may be creams, gels, solutions suspensions; the cyclodextrin compositions therein may further comprise non-polar solvents, waxes and other type of lipid-type agents, in 10% by weight (see col.5 lines 12-20 and 64-66 in particular); these oily components are known used for skin treatment (see col.5 lines 12-20 in particular). It is noted that non-polar solvents, waxes and other type of lipid-type agents are known to be an oil phase and also broadly encompass the instant oily components recited in claims herein.

Sanchez et al. does not expressly disclose a particular composition comprising an oil phase comprising long chain fatty acid monoglycerides and diglycerides, and a cyclodextrin component having one or more cyclodextrin. Sanchez et al. also does not expressly disclose this particular composition comprising at least 30% weight of γ-cyclodextrin and the ratio of an oil phase to cyclodextrins, 0.01 to 10, in the skin composition of the prior art.

Lucas et al. discloses a skin composition comprising uncomplexed cyclodextrins broadly, from about 0.1% to about 36%, by weight of the composition, and an oil phase selected from the group consisting of various agents such as fatty acids and esters, fatty alcohols (see col.4 line 38 to Table 1-2 at col.8-14). Lucas et al. discloses that the oil phase is present at a level of from about 0.1 to about 36% (see col.13 lines 10-12). Thus, at least the ratio of the oil phase to cyclodextrins would be 1:1 since either 0.1%:0.1% or 36%:36% equals to 1:1, within the instant claimed range.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein and to employ this particular composition comprising at least 30% weight of γ–cyclodextrin, and to optimize the ratio of the oil phase to cyclodextrins to 0.01 to 10.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ a particular composition comprising an oil phase and a cyclodextrin component having one or more cyclodextrin in the claimed method herein because it is known that the compositions of Sanchez et al. and/or Lucas et al.

comprising a cyclodextrin component having one or more cyclodextrin for skin and/or hair treatments therein may further comprise oils, waxes and other known lipid-type agents, which would encompass an oil phase and instant oily components recited in claims herein.

Therefore, one of ordinary skill in the art would have found it obvious to further employ an oil phase such as oils, waxes and other known lipid-type agents in a particular composition of Sanchez et al. based on the teachings of Lucas et al.

Moreover, one having ordinary skill in the art at the time the invention was made would have been motivated to employ this particular composition comprising at least 30% weight of γ–cyclodextrin and optimize the ratio of the oil phase to cyclodextrins since the effective amounts of cyclodextrins broadly including α-, β-, γ-yclodextrins with about 10% of oil phase in the topical compositions therein employed in the methods therein are known to be about 1-30% by weight according to Sanchez et al. Further, a skin composition comprising uncomplexed cyclodextrin from about 0.1% to about 36%, is known according to Lucas et al.

Further, the optimization of known effective amounts of known active agents to be administered according the disclosures of Sanchez et al. and Lucas et al., is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Argument

Applicant's arguments filed August 19, 2004 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action May 19, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that "it is clear that Lucas does not teach or suggest that this composition may be used to remove sebum and/or cerumen from the skin, let alone inhibit sebum production". Applicant's argument is not found convincing. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 SPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). See MPEP 2145.

In this case, Lucas et al. has been cited by the examiner as a secondary reference for its teaching that the skin composition comprising same cyclodextrins broadly, from about 0.1% to about 36%, by weight of the composition, and an oil phase selected from the group consisting of various agents such as fatty acids and esters, fatty alcohols wherein the oil phase is present at a level of from about 0.1 to about 36%; wherein at least the ratio of the oil phase to cyclodextrins would be 1:1 since either 0.1%:0.1% or 36%:36% equals to 1:1, within the instant claimed range, is known in treating skin broadly including treating **sebum** (see Lucas's patent, col.2 lines 29-30),

as Applicant admits (see Applicant's response at page 7). Hence, Lucas et al. discloses the employment of the same or substantially similar composition for the same or similar treatment such as treating sebum, as instantly claimed herein for reducing the production of sebum.

Applicant also argues that Sanchez et al. dose not teaches a single example of such a composition exemplified such as specific example of one specific hydrophobîc or lipophilic component, surfactant or emulsifier. Note that this rejection is not made under 102(b) rejection wherein the disclosure of the specific hydrophobîc or lipophilic component, surfactant or emulsifier would be required.

As discussed above, motivation to combine the teachings of the prior art cited herein to make the present invention is clearly seen, and no impermissible hindsight is seen. It must be recognized that any judgment on obviousness takes into account knowledge which was available and within the level of ordinary skill at the time the claimed invention was made. See In re McLaughlin , 170 USPQ 209 (CCPA 1971). See also MPEP 2145. Therefore, the claimed invention is clearly obvious in view of the prior art.

Additionally, as pointed out in the previous Office Action, the specification contains no clear and convincing evidence of nonobviousness or unexpected results for the claimed method herein over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-25, 27-29 and 31-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,428,796, for same reasons of record stated in the Office Action dated May 19, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a method for reducing or preventing a dull or dry feel on the skin following application of a cosmetic or dermatological composition comprising at least one cyclodextrin.

The claim of the instant application is drawn to a method for reducing the production of sebum or controlling at least one condition caused by increased sebum

production by applying a cosmetic or dermatological composition comprising a cyclodextrin component.

One having ordinary skill in the art at the time the invention would recognize these methods between in the patent and in the instant application are seen to substantially overlap since they have same method steps by applying the same active agent to skin or hair.

Thus, the instant claims 24-25, 27-29 and 31-38 are seen to be obvious over the claim 8 of U.S. Patent No. 6,428,796.

Response to Argument

Applicant's arguments filed August 19, 2004 with respect to this obviousness-type double patenting rejection (that is not provisional rejection as Applicant asserts) of record in the previous Office Action May 19, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that U.S. Patent No. 6,428,796 discloses a broad genus that is insufficient to maintain a obviousness type rejection under 103(a). Applicant's argument is not found convincing since 6,428,796 discloses the cosmetic or dermatological preparation comprising an oil phase and cyclodextrin, as instantly claimed (see 6,428,796, claims 1 and 6 in particular) and also have same method steps by applying the same active agent to skin or hair. Thus, the patent is deemed to be obvious over the claim 8 of U.S. Patent No. 6,428,796.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner, AU 1617
November 9, 2004